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Novel stroke treatment passes safety stage of UCI-led clinical trial

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A clinical research trial of a new treatment to restore brain cells damaged by stroke has passed an important safety stage, according to the UC Irvine neurologist who led the effort.

Dr. Steven C. Cramer said patients showed no ill effects after the sequential administration of growth factors encouraging the creation of neurons in stroke-damaged areas of the brain. All new drug treatments must pass this safety stage before doctors can study their effectiveness in subsequent studies.

Results of the phase IIa trial appear on the Web site of Stroke, a journal of the American Heart Association.

Within two days of suffering ischemic stroke, patients were put on a nine-day treatment course, starting with three once-daily injections of beta-hCG, a hormone that triggers the growth of neural stem cells. They then received three once-daily injections of erythropoietin, a hormone that directs these neural stem cells to become neurons.

Cramer, associate professor of neurology at UCI, said this combination of growth factors had been shown in animal studies to engender neuron creation leading to the recovery of a range of movement.

In the human safety study, he teamed with physicians from UC Irvine Medical Center; Hoag Memorial Hospital Presbyterian in Newport Beach, Calif.; and the University of Calgary in Canada. They

administered the treatment to 15 patients. No safety concerns were noted, and a majority of treated patients had minimal or no disability after three months.

A phase IIb clinical trial is now under way to compare the stroke therapy with placebo.

The study is supported by Stem Cell Therapeutics - a Canadian biotechnology company that conceived of an approach using this specific sequence of growth factors - and the National Center for Research Resources.

Provided by University of California - Irvine

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